In the United States Court of Federal Claims

FOR PUBLICATION

No. 23-629C
(Filed: January 22, 2025*)

VANDA PHARMACEUTICALS, INC.,	)
Plaintiff,	)
v.	)
UNITED STATES,	)
Defendant.	)

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* This opinion was originally filed under seal on January 7, 2025, in accordance with the protective order entered in this case. The Court provided the parties an opportunity to review the decision for any proprietary, confidential, or other protected information and submit proposed redactions. On January 17, 2025, both parties proposed a series of redactions. To be clear, the Court's adoption of the parties' proposed redactions should not be interpreted as sanctioning their assertions that the information is in fact a trade secret or otherwise qualifies as proprietary and/or confidential commercial information. Redactions are denoted using "{[redacted]}."

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OPINION AND ORDER

BONILLA, Judge.

Biopharmaceutical company Vanda Pharmaceuticals, Inc. (Vanda) alleges the U.S. Food and Drug Administration (FDA) improperly disclosed the brand manufacturer's trade secrets and confidential commercial and proprietary information to competitors seeking approval of generic drugs. Whether intentional or inadvertent, Vanda claims the FDA's disclosures of dissolution specifications and impurities testing and micronization information developed and learned in evaluating Vanda's new drug applications (NDAs) to three generic competitors in the course of reviewing their abbreviated new drug applications (ANDAs) constitute a Fifth Amendment taking (Count I) and breach of an implied-in-fact contract (Count II).

On January 18, 2024, the Court granted-in-part and denied-in-part the government's motion to dismiss Vanda's complaint for lack of subject matter jurisdiction and failure to state a claim upon which relief can be granted under Rules 12(b)(1) and 12(b)(6) of the Rules of the United States Court of Federal Claims (RCFC). *Vanda Pharms., Inc. v. United States*, 169 Fed. Cl. 196 (2024). Specifically, the Court dismissed Vanda's breach of contract claim "as either an implied-in-law contract outside the Court's jurisdiction or an improvidently pleaded claim that is facially implausible as a matter of law." *Id.* at 208. The Court also declared Vanda's claims time-barred as they relate to disclosures purportedly made to generic competitor Inventia Healthcare Private Limited (Inventia). *Id.* at 208–10. However, the Court denied the government's effort to construe and summarily dismiss Vanda's Fifth Amendment claim as an *unauthorized* taking. *Id.* at 205–06. Instead, the Court posed and deferred—until today—the following novel questions: whether Vanda can assert a cognizable property interest in an alternative dissolution specification *the FDA proposed to Vanda* during the drug approval process; whether and to what extent the FDA is precluded from inquiring about a generic drug manufacturer's impurity detection and micronization capabilities during the ANDA process simply because Vanda addressed them in its NDA; and the potential adverse impacts of crediting Vanda's proprietary claims on the FDA's administration of the NDA and ANDA processes. *Id.* at 206–07.

Pending before the Court is defendant's motion for judgment on the pleadings pursuant to RCFC 12(c) or, in the alternative, for summary judgment under RCFC 56

by operation of RCFC 12(d). For the reasons set forth below, defendant's motion for judgment on the pleadings is GRANTED.[1]

BACKGROUND

Vanda is an international biopharmaceutical company that researches, develops, and markets high-impact medications to address unmet medical needs. Founded in 2003, the corporation is headquartered in Washington, DC and maintains a self-described business model of "acquiring compounds that other companies failed to develop into treatments, identifying potential medical uses for them, devoting substantial resources to developing them, seeking FDA approval, and commercializing them." ECF 1 at 6–7. At issue in this case are two brand-name drugs developed by Vanda: Fanapt® (iloperidone) tablets approved to treat schizophrenia in adults, and Hetlioz® (tasimelteon) capsules approved to treat the circadian rhythm sleep disorder known as non-24-hour sleep-wake disorder. The FDA approved Vanda's NDAs relating to Fanapt® and Hetlioz® on May 6, 2009, and January 31, 2014, respectively. In the years since, the FDA considered and approved several ANDAs for generic versions of the brand-name drugs. Vanda's claims focus on the information FDA officials purportedly shared with manufacturers of these generics in evaluating and approving their applications.

I. Drug Approval Process

To market drugs in the United States, pharmaceutical companies must secure approval from the FDA for each new product pursuant to the Food, Drug, and Cosmetic Act (FDCA). 21 U.S.C. § 355(a) ("No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed [in accordance with this Act] is effective with respect to such drug."). The FDCA outlines the extensive data and information manufacturers must provide the Secretary of the U.S. Department of Health and Human Services (delegated to the FDA) in an NDA to demonstrate consumer safety and effectiveness and gain government approval to market a new drug. *See id.* § 355(b)(1)(A)(i)–(viii). In addition to the statutory requirements, by regulation, NDAs must include information on a product's chemistry, manufacturing, and controls, a meticulous technical review of the drug's manufacturing procedures, and "the specifications necessary to ensure the identity, strength, quality, purity, potency, and bioavailability of the drug product, including . . . acceptance criteria relating to . . . dissolution rate . . . ." 21 C.F.R. § 314.50(d)(1)(i)–(ii)(a). Of relevance to the brand-name and generic drugs in issue here is the requirement for dissolution specifications: the rate at which a drug dissolves. This data point is designed to measure consistency across batches and with the drug product presented from the clinical batch.

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[1] As discussed *infra*, in deciding this case under RCFC 12(c), the Court does not reach defendant's alternative dispositive motion under RCFC 56.

The FDA publishes a list of new drugs approved for safety and effectiveness in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book"), along with their associated patents and exclusivity information. *See Janssen Pharmaceutica, N.V. v. Apotex*, 540 F.3d 1353, 1355 (Fed. Cir. 2008) (citing 21 U.S.C § 355(b)(1), (c)(2) & (j)(2)(A)(i)). Drugs approved by the FDA, and included in the Orange Book, are referred to as "listed drugs." *See id.* "Inclusion of products in the Orange Book is independent of any current regulatory action being taken administratively or judicially against a drug product."[2]

The research and development phases and ensuing FDA approval process for a new drug is expensive and time consuming.[3] To incentivize pharmaceutical research and development as well as scientific and medical advancements, a pioneer or brand-name drug manufacturer generally receives a statutory period of market exclusivity following FDA approval. To further protect their intellectual property, manufacturers typically secure patents issued by the U.S. Patent and Trademark Office (USPTO)—including patents listed in the Orange Book—which, in some cases, impact the timing of generic drugs entering the market. A brand-name drug's market exclusivity does not always run concurrently with germane patent terms. Relevant to this case, market exclusivity can also be maintained by companies keeping confidential certain data and information in NDA disclosures (e.g., trade secrets, manufacturing methods and processes, production and sales distribution). *See* 21 C.F.R. § 314.430(g).

To better balance the vital public policy interests of encouraging new scientific development with competitors' ability to bring inexpensive generics to market, Congress passed the 1984 Drug Price Competition and Patent Term Restoration Act (commonly known as the Hatch-Waxman Act), 21 U.S.C. §355(j). *See Caraco Pharms. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1282 (Fed. Cir. 2008) ("The goal of the [Hatch-Waxman] Act is to [strike] a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market.") (quotation marks omitted). Under the Hatch-Waxman Act, upon filing an ANDA, the timing of generic drug approval is subject to patent and market exclusivity protections, and the ANDA must provide appropriate patent certifications or statements for each patent listed in the Orange Book.[4] But generic competitors may bypass much of the costly

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[2] *See* https://perma.cc/QLQ7-JPY4 (Orange Book Preface) (last visited Dec. 31, 2024).

[3] According to a 2015 report published by the Pharmaceutical Research and Manufacturers of America (PhRMA), on average, pharmaceutical manufacturers spend $2.6 billion over the course of more than a decade to bring a new drug to market. *See* https://perma.cc/WMZ4-YHAA at 4 (last visited Dec. 31, 2024); *cf. Fed. Trade Comm'n v. Actavis, Inc.*, 570 U.S. 136, 142 (2013) (describing FDA approval process as "long, comprehensive, and costly").

[4] An ANDA applicant must certify or state: (1) the patent information is not listed in the Orange Book (Paragraph I certification); (2) the patent listed in the Orange Book has expired (Paragraph II

and time-consuming research and development brand manufacturers undergo. *See* 21 U.S.C. § 355(j); *see also Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990) ("The ANDA applicant can substitute bioequivalence data for the extensive animal and human studies of safety and effectiveness that must accompany a full new drug application."). Through an ANDA, a competitor can secure FDA approval by demonstrating that the proposed generic drug shares the same active ingredients and bioequivalence as the brand-name drug. In doing so, competitors must provide data establishing that the administration, dosage, and strength of the generic drug is comparable to the brand-name drug. Through the streamlined ANDA process, generics effectively piggyback off the pioneer's proven research and development and due diligence from manufacturing, testing, and approving the brand-name drug.

The unauthorized disclosure of trade secrets and confidential and proprietary information by government officials who obtain that information in the course of their official duties or employment is prohibited under federal law. 18 U.S.C. § 1905. Governing FDA regulations pointedly state: "Data and information submitted or divulged to the [FDA] which fall within the definitions of a trade secret or confidential commercial or financial information are not available for public disclosure." 21 C.F.R. § 20.61(c); *accord id.* § 314.430(g) ("The following data and information in an application or abbreviated application are not available for public disclosure unless they have been previously disclosed to the public . . . or they relate to a product or ingredient that has been abandoned and they do not represent a trade secret or confidential commercial or financial information . . . : (1) Manufacturing methods or processes, including quality control procedures."). These protections are intended to promote full and transparent engagement between drug manufacturers and the FDA throughout the application and approval process. *See Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1010–11 (1984) (nondisclosure protections afforded under the Trade Secrets Act, 18 U.S.C. § 1905, are intended to protect "reasonable investment-backed expectation[s]").

II. Vanda's Brand-Name Drugs

Vanda filed NDA No. 22-192 for Fanapt® on September 27, 2007. In reviewing the application, the FDA rejected Vanda's proffered dissolution specification of Q = {[redacted]}% in {[redacted]} minutes and proposed an alternative rate of Q = {[redacted]}% in

certification); (3) the date the patent will expire (Paragraph III certification); and/or (4) the "[Orange Book-listed] patent is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the [generic] drug" (Paragraph IV certification). *See Report to Congress: The Listing of Patent Information in the Orange Book* at 8–9 (Dec. 2021). Although not relevant to deciding the issues before this Court, as noted *infra*, Vanda filed Paragraph IV certification and ANDA patent infringement litigation related to the brand-name and generic drugs discussed herein.

{[redacted]} minutes.[5] Vanda adopted the FDA's alternative dissolution criterion and the agency approved Fanapt® as safe and effective for consumers on May 6, 2009.

The FDA similarly rejected and proposed an alternative to Vanda's proffered dissolution specification for Hetlioz®. In NDA No. 205-677, filed on May 31, 2013, Vanda proffered a dissolution specification of Q = {[redacted]}% in {[redacted]} minutes. In reviewing Vanda's application, the agency found: "The proposed dissolution criterion is not supported by the data and is not acceptable." ECF 29-3 at 2, 6. The agency proposed an alternative rate of Q = {[redacted]}% in {[redacted]} minutes. Following Vanda's adoption of the FDA's alternative dissolution specification, on January 31, 2014, the agency approved Hetlioz® as safe and effective. Of note, Vanda's May 31, 2013 NDA included information it now claims is confidential and proprietary regarding the brand manufacturer's processes for detecting and controlling impurities in Hetlioz®'s active ingredient (i.e., tasimelteon), as well as "the methods through which it controls the size of tasimelteon crystals in its drug product" (also known as "micronization"). ECF 1 at 17.

III. ANDA Disclosures and Parallel Litigation

Following the Court's January 18, 2024 decision, Vanda's remaining claims arise from the FDA's alleged engagement with three competitors seeking approval to bring generic versions of Fanapt® and Hetlioz® to market. More specifically, Vanda alleges FDA officials disclosed the brand manufacturer's trade secret and confidential and proprietary information in ANDA correspondence with Lupin Limited and/or Lupin Pharmaceuticals, Inc. (collectively, Lupin), Teva Pharmaceuticals (Teva), and Apotex Corporation (Apotex).[6] The alleged disclosures, summarized below, relate to dissolution specifications and impurities testing and micronization information.

Lupin submitted ANDA No. 206890 for generic Fanapt® (iloperidone) tablets on May 8, 2014. The FDA rejected Lupin's proposed dissolution specification of Q = {[redacted]}% in {[redacted]} minutes and explained: "The firm's proposed specification . . . is too broad and not supported by their data and therefore not acceptable." ECF 7-2 at 1; ECF 29-2 at 2. Instead, the FDA proposed the same dissolution specification the agency recommended and approved for Fanapt® (i.e., Q = {[redacted]}% in {[redacted]} minutes). A contemporaneous note recorded in the agency file confirms an FDA official consulted the June 29, 2012 annual report produced for Fanapt® in determining what dissolution specification to recommend to Lupin. ECF 7-2 at 2 ("Reviewer's Note: the

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[5] As used in the above formula, "Q" denotes the "Quantity (Q) of active substance dissolved in a specified time, expressed as the percentage of product label claim." *See* National Institutes of Health, National Library of Medicine, *Developing Clinically Relevant Dissolution Specifications for Oral Drug Products—Industrial and Regulatory Perspectives* at 11 (Dec. 23, 2019), *available at* https://perma.cc/K8CH-TKC6 (last visited Dec. 31, 2024).

[6] As noted *supra*, Vanda's claims involving Inventia are time-barred.

reviewer checked the NDA Annual report for the above-mentioned specification for the [reference listed drug (RLD)].") (footnote omitted). Following Lupin's adoption of the FDA's alternative dissolution rate, its generic drug was formally approved as safe and effective on May 5, 2022.

In the interim, on January 31, 2018, Teva submitted ANDA No. 211601 for generic Hetlioz® (tasimelteon). The FDA rejected Teva's proposed dissolution specification of Q = {[redacted]}% in {[redacted]} minutes, instead recommending the rate previously proposed and approved for Hetlioz® (i.e., Q = {[redacted]}% in {[redacted]} minutes). Citing Vanda's U.S. Patent Application No. 20170190683A1 (Highly Purified Pharmaceutical Grade Tasimelteon) (published July 6, 2017),[7] the agency also inquired whether the generic manufacturer was capable of detecting, quantifying, and controlling specified impurities in the drug and, if so, instructed Teva to produce supporting data including limits of detection and quantification and linearity. The FDA also suggested that tasimelteon "may be subject to micronization" and, upon that assumption, directed the generic manufacturer to describe their micronization procedures and submit batch and stability data. ECF 29-7 at 2. Following Teva's adoption of the FDA's proposed alternative dissolution specification, and the generic manufacturer's submission of the requested impurity and micronization information, its generic drug was approved by the FDA as safe and effective on December 12, 2022.

Concomitantly, Apotex submitted ANDA No. 211607 for generic Hetlioz® (tasimelteon) on January 31, 2018. As with Teva's application, the FDA rejected Apotex's proposed dissolution specification of Q = {[redacted]}% in {[redacted]} minutes and, instead, recommended the rate previously proposed and approved for Hetlioz® (i.e., Q = {[redacted]}% in {[redacted]} minutes). Likewise, the FDA instructed Apotex to clarify its capabilities related to detecting, quantifying, and controlling specified impurities in the generic drug and, if applicable, instructed Apotex to produce supporting data, including limits of detection and quantification and linearity. The FDA also inquired:

> Please clarify whether your drug substance may be subject to any particle size reduction. If so, please provide the following:
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> a. [x-ray diffraction (XRD)] data for a batch of micronized drug substance.
> b. Stability data for a micronized batch of drug substance to ensure solid form stability.
> c. A detailed process description of the micronization procedure . . . .

ECF 29-6 at 3, *quoted in part in* ECF 1 at 38. On December 20, 2022, following Apotex's adoption of the FDA's proposed dissolution rate, and the manufacturer's

[7] *See* https://perma.cc/8TF3-E3H9 (last visited Dec. 31, 2024). The USPTO granted Vanda's patent (U.S. Patent No. 10,829,465 B2) on November 10, 2020. *See* https://perma.cc/8FEV-3W6L at 1 (last visited Dec. 31, 2024).

submission of the requested impurity data and micronization information, its generic drug was approved by the FDA as safe and effective.

Vanda alleges the FDA improperly disclosed the brand manufacturer's trade secrets and confidential and proprietary information by offering recommendations to generic competitors and, thus, breached its duty of confidentiality. More specifically, Vanda alleges the FDA's communications to the ANDA applicants regarding dissolution rates, impurities testing, and micronization revealed Vanda's confidential manufacturing information and caused economic injury to the brand manufacturer.[8] In sum, the FDA's alleged improper disclosures of Vanda's claimed confidential trade secrets and confidential and proprietary information to generic competitors, include:

Competitor	Pioneer Model	ANDA Submitted	FDA's Alleged Disclosures	FDA Approval
Lupin	Fanapt® (Iloperidone)	May 8, 2014	• Dissolution Rate	May 5, 2022
Teva	Hetlioz® (Tasimelteon)	Jan. 31, 2018	• Dissolution Rate • Impurities Testing • Particle Size/ Micronization	Dec. 12, 2022
Apotex				Dec. 20, 2022

Following the FDA's approval of these generic drugs, Vanda initiated ANDA patent infringement suits against the companies in federal district court.[9] Prior to

[8] Throughout its complaint, Vanda references additional competitors seeking to bring generic versions of Fanapt® and Hetlioz® to market, including Alembic Pharmaceuticals Ltd., MSN Pharmaceuticals Inc. (MSN), Roxanne Laboratories Inc. (n/k/a Hikma Labs Inc. and transferred to West-Ward Pharmaceuticals Corp.), and Taro Pharmaceutical Industries Ltd. To date, Vanda has not alleged any improper FDA disclosures to these generic manufacturers. Accordingly, any such claims are waived.

[9] *See, e.g.*, *Vanda Pharms., Inc. v. Teva Pharms. USA, Inc.*, No. 18-651, 2022 WL 17593282 (D. Del. Dec. 13, 2022) (judgment entered for defendants Teva and Apotex following four-day bench trial), *aff'd*, No. 23-1247, 2023 WL 3335538 (Fed. Cir. May 10, 2023), *cert. denied*, __ U.S. __, 144 S. Ct. 1393 (2024); *Vanda Pharms., Inc. v. Lupin Ltd.*, No. 15-1073 (D. Del. July 15, 2020) (voluntarily dismissed following settlement wherein Lupin deferred commercialization of generic product until Nov. 2, 2027); *compare Vanda Pharms., Inc. v. Inventia Healthcare PVT. LTD.*, No. 15-921 (D. Del. Dec. 5, 2024), *with* https://perma.cc/4WDE-ZFPS at 18–19 (Vanda's Quarterly Report (Form 10-Q) for the period ending March 31, 2022) (district court litigation remains pending despite confidential stipulation wherein Inventia has not launched or commercialized generic drug) (last visited Dec. 31, 2024); *see also* https://vandapharmaceuticalsinc.gcs-web.com/node/16186/html at 21 (Vanda's Q-10 for the period ending Sept. 30, 2024) (noting non-exclusive licensing agreement with MSN and Impax Laboratories, LLC to manufacture and market MSN's generic version of Hetlioz®) (last visited Dec. 31, 2024); *Vanda Pharms., Inc. v. Teva Pharms. USA, Inc.*, No. 23-152 (D. Del. filed Dec. 27, 2022) (pending patent litigation against Teva and Apotex); *Vanda Pharms., Inc. v. Teva Pharms. USA, Inc.*, No. 24-18 (D. Del. filed Jan. 29, 2023) (pending false advertising case against Teva); *Vanda Pharms. Inc. v. MSN Pharms. Inc.*, No. 24-815 (D. Del. filed July 12, 2024) (pending patent litigation against MSN).

commencing this action against the United States on May 1, 2023, Vanda also filed several civil suits against the FDA in federal district court.[10]

DISCUSSION

I. Standard of Review

"[W]hen considering a motion under RCFC 12(c), the court applies substantially the same test as it does for a motion to dismiss for failure to state a claim under RCFC 12(b)." *Sikorski Aircraft Corp. v. United States*, 122 Fed. Cl. 711, 719 (2015) (citing *Xianli Zhang v. United States*, 640 F.3d 1358, 1364 (Fed. Cir. 2011)). That is, "the court must assume 'each well-pled factual allegation to be true and indulge in all reasonable inferences in favor of the nonmovant.'" *Id.* (quoting *Owen v. United States*, 851 F.2d 1404, 1407 (Fed. Cir. 1988)). Legal conclusions presented as factual assertions are not, however, entitled to such deference. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citing *Papasan v. Allain*, 478 U.S. 265, 286 (1986)). Upon these premises, "[j]udgment on the pleadings is appropriate where there are no material facts in dispute and the [moving] party is entitled to judgment as a matter of law." *Forest Lab'ys, Inc. v. United States*, 476 F.3d 877, 881 (Fed. Cir. 2007) (citing *N.Z. Lamb Co. v. United States*, 40 F.3d 377, 380 (Fed. Cir. 1994)).

Relevant here, "[w]hen deciding a motion for judgment on the pleadings, the court may review 'the content of the competing pleadings, exhibits thereto, matters incorporated by reference in the pleadings, whatever is central or integral to the claim for relief or defense, and any facts of which the . . . court will take judicial notice.'" *T.H.R. Enters., Inc. v. United States*, 160 Fed. Cl. 236, 239 (2022) (quoting 5C Charles

[10] *See, e.g.*, *Vanda Pharms., Inc. v. FDA*, No. 23-1674 (D.D.C. Oct. 1, 2024) (Freedom of Information Act (FOIA) voluntarily dismissed following settlement); *Vanda Pharms., Inc. v. FDA*, No. 22-938 (D.D.C. Mar. 27, 2023) (summary judgment granted in favor of plaintiff in FOIA litigation); *Vanda Pharms., Inc. v. FDA*, No. 23-280 (D.D.C. filed Jan. 31, 2023) (Administrative Procedures Act (APA) challenge to FDA's decision to approve Teva's ANDA of generic Hetlioz® remains pending); *Vanda Pharms., Inc. v. FDA*, Nos. 22-3413, 22-3807, 22-3808, 24-2203 to -2205 (D.D.C. filed Nov. 7, 2022) (FOIA litigation remains pending); *Vanda Pharms., Inc. v. FDA*, No. 22-3052 (D.D.C. Aug. 29, 2023) (FOIA litigation voluntarily dismissed following settlement); *Vanda Pharms., Inc. v. FDA*, No. 22-2775 (D.D.C. Oct. 30, 2024) (summary judgment granted in favor of Vanda in APA challenge to FDA's alleged failure to issue a decision on Vanda's December 2018 Supplemental NDA for Hetlioz® and delay in scheduling a hearing); *Vanda Pharms., Inc. v. FDA*, No. 22-1432 (D.D.C. Aug. 2, 2023) (summary judgment for defendant in APA challenge to FDA's decision denying Vanda "Fast Track" designation for tradipitant–a drug to treat gastroparesis), *appeal docketed*, No. 23-5200 (D.C. Cir. Sept. 11, 2023); *Vanda Pharms., Inc. v. FDA*, No. 22-1405 (D.D.C. June 21, 2023) (FOIA litigation voluntarily dismissed following settlement); *Vanda Pharms., Inc. v. FDA*, No. 23-2325 (D.D.C. Apr. 22, 2024) (same); *Vanda Pharms., Inc. v. FDA*, No. 23-2884 (D.D.C. Jan. 17, 2024) (same); *Vanda Pharms., Inc. v. FDA*, No. 23-2327 (D.D.C. filed Aug. 11, 2023) (FOIA litigation pending); *Vanda Pharms., Inc. v. FDA*, No. 23-2812 (D.D.C. filed Sept. 25, 2023) (APA challenge to FDA's approval of MSN's tasimelteon ANDA remains pending).

A. Wright & Arthur R. Miller, Federal Practice and Procedure § 1367 (3d ed. 2004)). Documents considered "central to the complaint" can include exhibits "whose contents are alleged in the complaint and whose authenticity no party questions, but which are not physically attached to the pleading." *Toon v. United States*, 96 Fed. Cl. 288, 298–99 (citing cases). The facts material to deciding this case are rooted in the detailed accounts included in Vanda's pleading, matters of public record, or otherwise uncontroverted. Accordingly, the Court need not convert defendant's motion to one for summary judgment.[11] *See id.* at 299.

II. Fifth Amendment Taking

The Takings Clause of the Fifth Amendment provides: "nor shall private property be taken for public use, without just compensation." U.S. Const. AMEND. V, cl. 4. In determining whether a viable takings claim has been adequately pled, courts apply a two-part test. "First, the court determines whether the claimant has identified a cognizable Fifth Amendment property interest that is asserted to be the subject of the taking. Second, if the court concludes that a cognizable property interest exists, it determines whether that property interest was 'taken.'" *Acceptance Ins. Cos. v. United States*, 583 F.3d 849, 854 (Fed. Cir. 2009) (citing cases). Where, as here, the claimant fails to assert a cognizable property interest, the court's inquiry begins and ends on the first step. *Fishermen's Finest, Inc. v. United States*, 59 F.4th 1269, 1275 (Fed. Cir. 2023) (quoting *Am. Pelagic Fishing Co. v. United States*, 379 F.3d 1363, 1372 (Fed. Cir 2004)).

As explained by the United States Court of Appeals for the Federal Circuit:

> The Constitution neither creates nor defines the scope of property interests compensable under the Fifth Amendment. *Bd. of Regents of State Colleges v. Roth*, 408 U.S. 564 (1972). Instead, "existing rules and understandings" and "background principles" derived from an independent source, such as state, federal, or common law, define the dimensions of the requisite property rights for purposes of establishing a cognizable taking. *Lucas v. S.C. Coastal Council*, 505 U.S. 1003, 112 (1992).

[11] The Court rejects Vanda's contention that the issues raised in this case are too fact-intensive to be resolved under RCFC 12(c). *See Am. Pelagic Fishing Co. v. United States*, 379 F.3d 1363, 1371 (Fed. Cir. 2004) ("Whether a compensable taking has occurred is a question of law based on factual underpinnings.") (citing *Maritrans Inc. v. United States*, 342 F.3d 1344, 1350–51 (Fed. Cir. 2003)); *Econ. Rsch. Servs. v. Resolution Econ., LLC*, 208 F. Supp. 3d 219, 232–33 (D.D.C. 2016) ("Although the question of whether a piece of information is a trade secret is typically a question of fact, information is not a trade secret as a matter of law if it is 'easily ascertainable by the public or generally known within an industry.'") (citation omitted).

Conti v. United States, 291 F.3d 1334, 1340 (Fed. Cir. 2002) (footnote omitted). Under these principles, cognizable property interests extend to both tangible and intangible property, including commercial data. *Acceptance*, 583 F.3d at 854 ("Real property, tangible property, and intangible property, all may be the subject of takings claims.").

Over forty years ago, the United States Supreme Court expressly extended Fifth Amendment protections to legally recognized trade secrets. *Monsanto*, 467 U.S. at 1003–04. In *Monsanto*, the Supreme Court considered whether a pesticide inventor, developer, and producer had a cognizable property interest in research and test data the company generated and submitted to the U.S. Environmental Protection Agency (EPA) during the pesticide registration process. *Id.* at 1000–01. As authorized by statute, EPA officials used the submitted data to evaluate a competitor's registration application and then published certain data. *Id.* at 990 (citing Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136 et seq.). Citing state law defining property as including trade secrets protected from disclosure, the Supreme Court held that the claimant had a vested property interest in the intangible asset. *Id.* at 1002–04.

As in *Monsanto*, applicable local law recognizes trade secrets consistent with the definition of property included in the Restatement of Torts. In Washington, DC where Vanda is headquartered:

> "Trade secret" means information, including a formula, pattern, compilation, program, device, method, technique, or process, that:
>
> (A) Derives actual or potential independent economic value, from not being generally known to, and not being readily ascertainable by, proper means by another who can obtain economic value from its disclosure or use; and
>
> (B) Is the subject of reasonable efforts to maintain its secrecy.

D.C. Code § 36-401(4) (2024).[12] Federal law includes a similar definition:

> [T]he term "trade secret" means all forms and types of financial, business, scientific, technical, economic, or engineering information, including patterns, plans, compilations, program devices, formulas, designs, prototypes, methods, techniques, processes, procedures, programs, or codes, whether tangible or intangible, and whether or how stored, compiled, or memorialized physically, electronically, graphically, photographically, or in writing if–

[12] Under Maryland state law, where the FDA is headquartered, the definition of trade secret is nearly identical. *See* Md. Code, Com. Law § 11-1201(e).

> (A) the owner thereof has taken reasonable measures to keep such information secret; and
>
> (B) the information derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, another person who can obtain economic value from the disclosure or use of the information . . . .

18 U.S.C. § 1839(3) (2016). Comparatively cited in *Monsanto*, the Restatement of Torts includes the following definition: "A trade secret may consist of any formula, pattern, device or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it." Restatement (First) of Torts § 757 (1939), *quoted with approval in* 467 U.S. at 1001–02. These definitions, as well as the intended confidentiality of trade secret information submitted to the FDA as part of the drug approval process, is codified by the federal agency's regulations. 21 C.F.R. § 20.61(a) (2022) ("A trade secret may consist of any commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. There must be a direct relationship between the trade secret and the productive process."); *id.* § 20.61(c) ("Data and information submitted or divulged to the [FDA] which fall within the definitions of a trade secret or confidential commercial or financial information are not available for public disclosure.").[13]

Notwithstanding the foregoing, Vanda fails to plead a viable Fifth Amendment taking based upon the claimed government disclosures of dissolution specifications and impurities testing and micronization information. The dissolution specifications ultimately adopted for Fanapt® and Hetlioz® were not developed by Vanda or submitted to the FDA. Rather, they were generated by the FDA and proposed to and accepted by Vanda during the NDA process in order to secure approval to market.[14] In turn, the impurities testing and micronization information related to the active pharmaceutical ingredient in Hetlioz® (i.e. tasimelteon) was already in the public domain at the time of the agency's alleged disclosures: Vanda included the cited data in a publicly filed patent application six months before the FDA reportedly used the

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[13] The FDA regulation similarly defines (and protects) confidential and privileged commercial and financial information as "valuable data or information which is used in one's business and is of a type customarily held in strict confidence or regarded as privileged and not disclosed to any member of the public by the person to whom it belongs." 21 C.F.R. § 20.61(b).

[14] During oral argument, the government acknowledged that a dissolution specification proffered by a drug manufacturer and approved (as originally submitted) by the FDA "may qualify for some [nondisclosure] protection." ECF 57 at 44–45. The government immediately qualified the statement, explaining: "That's not the case here. That's not to say that we are conceding the matter, but we're not making this argument. I think [the Court's hypothetical presents] a much more complicated argument." *Id.* at 45.

information in reviewing ANDAs. Accordingly, defendant is entitled to judgment on the pleadings.[15, 16]

A. Dissolution Specifications

Whether an adopted dissolution specification constitutes a property interest cognizable under the Fifth Amendment is an issue of first impression. In answering this question in the negative, the Court examines Vanda's claims in the context of the governing regulatory scheme, applicable federal and state law, and relevant caselaw. None support Vanda's claim.

FDA regulations define trade secret as "the end product of either innovation or substantial effort," adding that "[t]here must be a direct relationship between the trade secret and the productive process." 21 C.F.R. § 20.61(a). The dissolution specifications in issue do not satisfy either criterion. Vanda did not develop or propose the approved rates to the FDA. Instead, as captured in the chart below, the FDA rejected Vanda's proffered dissolution rates for both Fanapt® and Hetlioz® and proposed an alternative for each brand-name drug. Vanda then adopted the FDA-recommended dissolution rates and secured NDA approval.

Drug	**Vanda's Proposed Rate**	**FDA's Alternative Rate**
Fanapt®	Q = {[redacted]}% at {[redacted]} minutes	Q = {[redacted]}% at {[redacted]} minutes
Hetlioz®	Q = {[redacted]}% at {[redacted]} minutes	Q = {[redacted]}% at {[redacted]} minutes

While Vanda developed the brand-name drugs, the trade secret and confidential and proprietary information claimed to have been taken by the government was, in fact, proposed and recommended *to Vanda by the FDA*. Though the FDA used information included in Vanda's NDA to generate the alternative rates, the revised dissolution specifications cannot be said to be the "end product" of Vanda's innovation or effort, let alone directly related to Vanda's productive process. Logic dictates that the

[15] The Court rejects Vanda's assertion that the pending dispositive motion must be limited to trade secret claims due to defendant's alleged failure to separately address Vanda's simultaneous assertions that the contested information also qualifies as confidential and proprietary. Throughout these proceedings the government's position has been clear: no matter the label, Vanda fails to assert a cognizable property interest in the contested dissolution specifications and impurity testing and micronization information.

[16] In resolving the pending dispositive motion, the Court similarly rejects defendant's blanket assertion that Vanda's reported disclosures of the subject dissolution specifications in collateral litigation extinguishes plaintiff's claims that the information qualifies as a trade secret and confidential and proprietary information. Vanda's reported disclosures (whether inadvertent or intentional) took place in early 2023—over four years *after* the FDA's purportedly shared the information with Vanda's competitors and over a year *after* the generic drugs hit the marketplace. By then, any claimed damage was done. *See CardioVention, Inc. v. Medtronic, Inc.*, 483 F. Supp. 2d 830, 835 (D. Minn. 2007) ("[I]nformation that become[s] publicly available after the time of the misappropriation is irrelevant to the existence of a trade secret at the time of the misappropriation.") (citing *B. Braun Med., Inc. v. Rogers*, 163 F. App'x 500, 505–06 (9th Cir. 2006)).

government cannot be credibly accused of taking information generated by a federal agency in the course of its regulatory review and then proposed to the applicant to secure regulatory approval. This case is readily distinguishable from *Monsanto*, where the contested trade secret data was wholly generated by the claimant and presented to the regulatory agency. *See* 467 U.S. at 1002–03 ("Th[e] general perception of trade secrets as property is consonant with a notion of 'property' that extends beyond land and tangible goods and includes the products of an individual's 'labour and invention.'") (citation omitted); *cf. United States v. Fuller*, 409 U.S. 488, 492 (1973) ("[T]he Government as condemnor may not be required to compensate a condemnee for elements of value that the Government has created, or that it might have destroyed under the exercise of governmental authority other than the power of eminent domain."), *cited in Conti*, 291 F.3d at 1340–41 (no cognizable property right lies in increased property value attributable to revokable permits and licenses).[17]

Further highlighting the implausibility of Vanda's claimed compensable property interest in the dissolution specifications adopted to secure regulatory approval is the disconnect between the alleged trade secret and the company's productive process. As this case illustrates, dissolution specifications are not unique to the end product or the productive process employed. In adopting the alternative FDA-recommended dissolution specifications, nothing in the record suggests—nor has there been any representation—that Vanda altered the composition of Fanapt® or Hetlioz® or modified the production of the brand-name drugs. It cannot be said that there is a direct relationship between the dissolution specification and the productive process if an identical manufacturing process can yield multiple dissolution specifications. In response, Vanda argues the company's proposed dissolution rates were close to the ones the FDA ultimately required: a {[redacted]}-minute delta for Hetlioz® and a {[redacted]}-percent dissolution delta for Fanapt®. Proposing dissolution specifications requires more precision than horseshoes and hand grenades particularly where, as here, Vanda claims that the rates are the company's trade secrets and confidential and proprietary information.

In the realm of dissolution specifications for immediate release solid oral drugs, the array of dissolution specifications is narrow. The specification is generally limited to the following combinations: 75%, 80%, or 85% over 15-, 30-, or 45-minutes.[18] As

[17] On this point, Vanda's citation to *Carpenter v. United States*, 484 U.S. 19 (1987), and *Formax, Inc. v. United States*, 841 F.2d 388 (Fed. Cir. 1988), is not persuasive. In *Carpenter*, the contested confidential business information was the contents of as yet published financial columns generated by a newspaper reporter, who repeatedly misappropriated the information in a stock tip fraud conspiracy. 484 U.S. at 20–23. *Formax* involved a terminated employee's theft of company-generated drawings claimed to be trade secrets. 841 F.2d at 389. The courts in both matters noted that the claimant owned the contested information. *Carpenter*, 484 U.S. at 26; *Formax*, 841 F.2d at 389.

[18] *See* McAllister et al., *Developing Clinically Relevant Dissolution Specifications for Oral Drug Products—Industrial and Regulatory Perspectives*, PHARMS. at 4 (Dec. 2019) ("For immediate release solid oral dosage forms . . . the mean dissolution of 12 units minus 10%, rounded to the nearest 5%,

illustrated in the chart below, the dissolution specifications included in the generic manufacturers' ANDAs were about as close as Vanda's original NDA proposals to the FDA-sanctioned rates. And, in Apotex's case, the generic manufacturer was more closely aligned with the FDA's alternative dissolution specification than Vanda.

Drug	Vanda NDA	Generic ANDA	FDA Approved
Fanapt®	Q = {[redacted]}% at {[redacted]} minutes	Lupin: Q = {[redacted]}% at {[redacted]} minutes	Q = {[redacted]}% at {[redacted]} minutes
Hetlioz®	Q = {[redacted]}% at {[redacted]} minutes	Teva: Q = {[redacted]}% at {[redacted]} minutes Apotex: Q = {[redacted]}% at {[redacted]} minutes	Q = {[redacted]}% at {[redacted]} minutes

Put simply, the FDA-generated and recommended dissolution specifications lack the regulatory hallmarks of a drug manufacturer's trade secret or confidential and proprietary information.[19]

Vanda's claims fare no better under federal and state law. As quoted *supra*, relevant here, federal and Washington, DC (and Maryland) trade secret laws were enacted to protect scientific formulas, methods, techniques, and processes that derive independent economic value from their secrecy. 18 U.S.C. § 1839(3); D.C. Code § 36-401(4); Md. Code, Com. Law § 11-1201(e); *cf. Synopsys, Inc. v. Risk Based Sec., Inc.*, 70 F.4th 759, 771 (4th Cir. 2023) ("[F]or information to constitute a 'trade secret' under Virginia and federal law, it must '[d]erive[ ] independent economic value' from its secrecy.") (quoting Va. Code § 59.1-336; 18 U.S.C. § 1839(3)(B)). Contrary to the arguments advanced by Vanda, there is no inherent independent economic value in a drug's dissolution specification. Nor can the FDA be reasonably expected to withhold from generic manufacturers the dissolution specifications generated by the agency and provided to the brand manufacturer in carrying out its regulatory obligation of ensuring bioequivalence between brand-name and generic drugs.

Vanda's assertion that the FDA-recommended dissolution specification of a brand-name drug provides generic manufacturers significant insight and information about the manufacturing process is undermined by the reality of the situation and

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should be used as the Q value and set as Q = 75%, 80% or 85% in 15/30/45 min."), *available at* https://perma.cc/5ZFY-BCQJ (last visited Dec. 31, 2024); U.S. Department of Health & Human Services, Food & Drug Administration, Center for Drug Evaluation & Research, *Guidance for Industry: Dissolution Testing and Acceptance Criteria for Immediate-Release Solid Oral Dosage Form Drug Products Containing High Solubility Drug Substances*, at 8 (Aug. 2018) ("For immediate release solid oral drug products containing a high solubility drug substance . . . the dissolution criterion is Q=80% in 30 minutes."), *quoted in Collaza v. Johnson & Johnson Consumer, Inc.*, No. 23-6030, 2024 WL 3965933, at *2 (S.D.N.Y. Aug. 27, 2024), *appeal docketed*, No. 24-2568 (2d Cir. Sept. 27, 2024), *and Musikar-Rosner v. Johnson & Johnson Consumer Inc.*, No. 23-11746, 2024 WL 3596897, at *4 (D. Mass. July 31, 2024), *and Bischoff v. Albertsons Cos.*, 678 F. Supp. 3d 518, 524 (S.D.N.Y. 2023). During oral argument Vanda's counsel suggested that a 20- or 60-minute interval could be used, raising the total standard combinations from nine to fifteen. ECF 57 at 94–95.

[19] As discussed *infra*, Vanda's assertions that the FDA-generated and recommended dissolution specifications qualify as the company's confidential and privileged information seemingly fail for the additional reason that they have no inherent independent value as required under 21 C.F.R. § 20.61(b).

the facts presented. Because the brand-name drug is first to market, generic manufacturers can determine, or at least approximate, the dissolution rate through independent lab testing. This is particularly true where, as here, the dissolution test method is publicly available for replication.[20] Moreover, the record presented strongly suggests that, like Vanda, none of the generic manufacturers modified the composition, dosage, form, strength, or performance characteristics of their drugs after the FDA recommended an alternative dissolution specification. They simply revised their originally proposed specifications to reflect the FDA-generated and approved dissolution specification.[21] As such, no independent economic value can be readily ascribed to the claimed information.

Vanda's assertions of proprietary secrecy in the dissolution specifications in issue further run afoul of the FDA's regulatory authority and obligations of ensuring bioequivalence in brand-name and generic drugs and in uniformly treating market competitors. To this end, the FDA's dissolution testing guidelines publicly state: "In the case of a generic drug product, the dissolution specifications are generally the same as the reference listed drug (RLD) [or brand-name drug]."[22] It is seemingly impractical if not impossible for the FDA to align dissolution specifications between brand-name and generic drugs if the agency is prohibited from accessing or referencing the NDA-approved dissolution specification in its subsequent ANDA review.[23] As initially raised in the Court's prior decision in this matter:

> [W]ithout comparing the data and information of an approved NDA to the proposed data and information included in a generic's ANDA under review, the FDA may authorize inconsistent results. In that case, Vanda might claim the FDA improvidently delayed the brand[-]name product to market or, in the alternative, hastened the generic drug's review and approval. The FDA could also reject a generic's proposed dissolution

[20] *Compare* ECF 29-2 at 3 (Lupin dissolution testing data), *with* U.S. Department of Health & Human Services, Food & Drug Administration, Center for Drug Evaluation & Research, *Guidance for Industry: Dissolution Testing and Acceptance Criteria for Immediate-Release Solid Oral Dosage Form Drug Products Containing High Solubility Drug Substances*, at 7–8 (Aug. 2018) (Standard Dissolution Testing Conditions).

[21] *Compare* ECF 29-1 at 102–03 (Fanapt®) *and* ECF 29-3 at 6–9 (Hetlioz®), *with* ECF 29-2 at 2–6 (Lupin) *and* ECF 29-4 at 3–4 (Teva) *and* ECF 29-5 at 8 (Apotex). This comparative information was referenced in Vanda's complaint. *See* ECF 1 at 19–20, 33.

[22] *See* U.S. Department of Health & Human Services, Food & Drug Administration, Center for Drug Evaluation & Research, *Guidance for Industry: Dissolution Testing of Immediate Release Solid Oral Dosage Forms* at 3 (Aug. 1997), *available at* https://perma.cc/K4QU-3EXX (last visited Dec. 31, 2024).

[23] On this point, agency guidance further provides: "Once the specifications are established in an NDA, the dissolution specifications for batch-to-batch quality assurance are published in the United States Pharmacopeia (USP) as compendial standards, which become the official specifications for all subsequent [immediate release] products with the same active ingredients." *Id.* at 2. During oral argument counsel clarified that Vanda did not consent to the "optional" USP publication. ECF 57 at 27 (government), 81–82 (Vanda).

> specification previously accepted for a brand manufacturer or another generic, subjecting the agency to accusations of delaying a generic drug's approval.

Vanda, 169 Fed. Cl. at 206. *See Am. Wild Horse Preservation Campaign v. Perdue,* 873 F.3d 914, 927–28 (D.C. Cir. 2017) (federal agency's failure to acknowledge or explain departure from past practice found "arbitrary and capricious") (citing cases). Despite advanced notice of the Court's practical considerations, Vanda has failed to allay these concerns.[24] The FDA-recommended dissolution specifications adopted by Vanda to gain approval to bring the brand-name drugs to market necessarily served as the benchmarks for the FDA's subsequent ANDA reviews and approvals of generic drugs. As such, Vanda's claimed proprietary interest in this regulatory-generated data is unfounded.[25]

B. Impurities Testing

On July 6, 2017, Vanda publicly filed U.S. Patent Application No. 2017/0190683 A1, titled Highly Purified Pharmaceutical Grade Tasimelteon. The abstract provides: "A process for preparing a batch of highly purified, pharmaceutical grade tasimelteon comprises analyzing a batch of tasimelteon synthesized under [good manufacturing practice (GMP)] conditions for the presence of one or more identified impurities."[26] Under Field of the Invention, Vanda's patent application states: "The disclosure relates generally to the synthesis of tasimelteon. In some embodiments, impurities, which may be by-products or degradation products, are analyzed and controlled in order to keep the impurities below pre-set specifications."[27]

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[24] In fact, in ongoing collateral litigation, Vanda seeks to invalidate the FDA's approval of MSN's generic version of Hetlioz® (tasimelteon), citing the federal agency's claimed failure to compare the proffered dissolution specification and other bioequivalence data to the brand-name drug (a/k/a RLD) and an FDA-approved generic drug. *See Vanda Pharms., Inc. v. FDA*, No. 23-2812 (D.D.C.) (ECF 24-1 at 33 filed Apr. 22, 2024). The government's counterargument in that case—that "there is no *requirement* that the agency look outside the confines of the ANDA" so long as the FDA performs the necessary due diligence and treats all applicants equally, *see id.* (ECF 27-1 at 21–22 filed May 20, 2024) (emphasis in original)—does not move the proverbial needle on this issue in Vanda's direction. *See* ECF 57 at 106–07 ("THE COURT: So to the extent that they are arguing the opposite of what they're arguing today, Vanda seems to be doing the same of no, no, you have to look at that stuff and you have to make sure that they're bioequivalent.").

[25] The fact that the FDA redacted the dissolution specifications in response to a FOIA request—perhaps out of an abundance of caution—does not confer on Vanda a compensable Fifth Amendment property interest in the information. Put simply, an agency's FOIA redaction policies and practices—as well as a specific employee's good faith adherence to them—are not dispositive regarding the Court's independent conclusion that the FDA-generated and recommended dissolution specifications are not trade secrets or protected confidential or proprietary information.

[26] *See* https://perma.cc/NM95-EZ9Z at 1 (last visited Dec. 31, 2024). As noted *supra*, the USPTO granted Vanda's patent (U.S. Patent No. 10,829,465 B2) on November 10, 2020.

[27] *Id.* at 2.

The Summary of the Invention and Detailed Description of the Invention go on to identify specific impurities generally found in tasimelteon through testing, claiming Vanda's ability to purify the bulk drug substance to within fixed acceptable levels.[28]

Six months later, on January 31, 2018, Teva submitted ANDA No. 211601 for generic Hetlioz® (tasimelteon). That same day, Apotex followed with ANDA No. 211607. Citing Vanda's July 6, 2017 patent application, the agency inquired whether Teva and Apotex were likewise capable of detecting, quantifying, and controlling specified impurities in the drug and, if so, instructed the generic manufacturers to produce supporting data, including limits of detection and quantification and linearity. Vanda maintains that referencing the brand manufacturer's patent application in the course of Teva's and Apotex's ANDA reviews improperly or, at a minimum, improvidently revealed a trade secret and proprietary and confidential information: the fact that Vanda {[redacted]} in its production of Hetlioz®.

Under similar circumstances, the Supreme Court stated: "Information that is public knowledge or that is generally known in an industry cannot be a trade secret. If an individual discloses his trade secret to others who are under no obligation to protect the confidentiality of the information, or otherwise publicly discloses the secret, his property right is extinguished." *Monsanto*, 467 U.S. at 1002 (citations omitted). In the patent context, the Federal Circuit aptly explained:

> "It is well established that disclosure of a trade secret in a patent places the information comprising the secret into the public domain. Once the information is in the public domain and the element of secrecy is gone, the trade secret is extinguished and the patentee's only protection is that afforded under the patent law."

Ultimax Cement Mfg. Corp. v. CTS Cement Mfg. Corp., 587 F.3d 1339, 1355 (Fed. Cir. 2009) (quoting *Stutz Motor Car of Am. v. Reebok Int'l*, 909 F. Supp. 1353, 1359 (C.D. Cal. 1995) (additional citation omitted)). Comparing the detailed information included in Vanda's patent application with the more general inquiry the FDA posed to Teva and Apotex regarding the generic manufacturers' comparable capabilities does not yield the improper disclosure of any novel or unknown part of Vanda's production process. *See, e.g.*, *Strategic Directions Grp., Inc. v. Bristol-Myers Squibb Co.*, 293 F.3d 1062, 1065 (8th Cir. 2002) ("In some cases, a novel or unique combination of elements may constitute a trade secret. However, as here, 'mere variations on widely used [information] cannot be trade secrets.' . . . 'Simply to assert a trade secret resides in some combination of otherwise known data, is not sufficient . . . .'") (citations omitted). Accordingly, Vanda's claimed trade secret and confidential and proprietary interest in the brand manufacturer's self-publicized impurities

[28] *Id.* at 3–12.

testing information involving the precise drug in issue (tasimelteon) fails to plead a viable Fifth Amendment takings claim.

C. Micronization

Next, Vanda claims the FDA further disclosed to Teva and Apotex the brand manufacturer's trade secret and confidential and proprietary interest in particle size control techniques used in milling the active pharmaceutical ingredient in Hetlioz® (tasimelteon). In support, Vanda cites the FDA's July 12, 2018 responses to Teva's and Apotex's January 31, 2018 ANDAs, wherein the federal agency: suggested that tasimelteon "may be subject to micronization" and, upon that assumption, directed the generic manufacturers to describe their micronization procedures and submit batch and stability data. ECF 29-7 at 2 (FDA letter to Teva); *accord* ECF 29-6 at 3 (FDA letter to Apotex inquiring whether their generic drug "may be subject to any particle size reduction"). Vanda also cites an internal FDA memorandum reviewing Teva's ANDA, wherein the federal agency documented: "The [generic drug substance (DS)] is {[redacted]} . . . . [The reference listed drug (RLD)] is {[redacted]}."[29] ECF 47-4 at 4.

Vanda's micronization-based claims fail for the same reason as their impurities testing claims: Vanda's July 6, 2017 Highly Purified Pharmaceutical Grade Tasimelton patent application, discussed *supra*, specifies the brand manufacturer's particle size reduction techniques—including {[redacted]}. In fact, the publicly filed patent application describes the particle size reduction techniques {[redacted]} in preparing highly purified, pharmaceutical grade tasimelteon in greater detail than included in the cited FDA correspondence.[30] The fact that Teva's generic drug is {[redacted]} rather than {[redacted]} does not preclude the FDA from inquiring about comparable capabilities derived from other techniques highlighted in related patent applications or discussed in scientific literature. Under the caselaw summarized in the previous section, no cognizable Fifth Amendment takings claim can be based on a government agency's regulatory use of information already made public by its reported owner.[31]

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[29] Nothing in the record presented suggests the internal FDA memorandum was shared with Vanda's competitors or otherwise made public. Further, contrary to Vanda's current assertion, the Court does not ascribe nefarious intent to the agency's decision to redact the above-quoted second sentence in a collateral FOIA response. ECF 47-4 at 4 ("NOT for FOIA: RLD is {[redacted]}"). The unredacted version of this document was produced in discovery in this case.

[30] *See, e.g.*, https://perma.cc/8TF3-E3H9 at 10 ("It has been found that use of a jet mill and a dry nitrogen atmosphere is advantageous in achieving uniform particle size with good handling characteristics and minimal loss.") (last visited Dec. 31, 2024); *id.* at 11–12 ("A process for preparing a batch of highly purified tasimelteon that comprises . . . milling the tasimelteon to meet particle size specifications . . . .").

[31] Vanda's reliance upon a cherry-picked quote in *Delice Global, Inc. v. Coco Int'l, Inc.*, No. 90-3541, 2009 WL 2905466 (D.N.J. Sept. 9, 2009), is misplaced and otherwise unpersuasive. In *Delice Global*,

III. Leave to Amend

In closing out its brief, Vanda generally requests leave to amend its complaint to allege additional facts in the event the Court is inclined to grant defendant's dispositive motion. Vanda does not, however, proffer what those facts are or otherwise tie them to the record currently before the Court or the fundamental issues resolved today. Three months later—after the Court scheduled oral argument—Vanda filed a motion to compel discovery. The discovery demanded relates back to Vanda's initial request to produce documents, propounded in February 2024 following the Court's partial dismissal of Vanda's claims. As with the conditional request to amend, Vanda's motion to compel is not focused on the foundational issues raised in the dispositive motion addressed herein—i.e., Vanda's claimed compensable property interests in the dissolution specifications and impurities testing and micronization information. Instead, the broad production request seeks documents pertaining to the FDA's regulatory review of Vanda's NDAs and several generics' ANDAs as well as the federal agency's suspected disclosures to third parties.[32] Vanda's entitlement to these documents presumes that which the Court finds critically lacking: a compensable Fifth Amendment property interest. This litigative approach is particularly troubling given that the Court placed Vanda on formal written notice a year ago regarding the perceived shortcomings of the brand manufacturer's claimed property interests in the contested data and information.

To be clear, defendant's apparent slow-walking and eventual suspension of the FDA's responses to Vanda's discovery request does not represent the government's finest hour. Prior to filing the dispositive motion decided herein, defendant informally requested a stay of discovery. It was denied. In a compromise proposed by the Court, defendant agreed to continue producing documents in response to Vanda's pending production request in exchange for plaintiff's agreement not to propound further discovery. The arrangement was expected to continue throughout briefing and the Court's resolution of defendant's dispositive motion. After several months of production, and coinciding with the completion of briefing in July 2024, document production unjustifiably ceased. Following an exchange of formal discovery letters initiated by plaintiff, and the scheduling of oral argument on defendant's

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the district court distinguished between a product's recipe and the patented device used to manufacture it, stating: "a patent regarding an instrument of production does not preclude the assertion of a trade secret concerning the formula of production." *Id.* at *5. Here, the FDA did not share the formula Vanda used to produce Hetlioz®. Rather, the regulatory agency simply asked the generic manufacturers about their respective capabilities regarding what Vanda publicly described as "advantageous" techniques "in achieving uniform particle size [in tasimelton] with good handling characteristics and minimal loss." *Compare* ECF 29-7 at 2 (FDA letter to Teva) *and* ECF 29-6 at 3 (FDA letter to Apotex), *with* https://perma.cc/8TF3-E3H9 at 10 (Vanda's patent application) (last visited Dec. 31, 2024).

[32] Vanda's production request also seeks documents related to drugs never in issue in this case as well as claims previously dismissed by this Court.

dispositive motion,[33] the discovery dispute was brought to the Court's attention. The more judicious approach would have been for the government to file a renewed (formal) motion to stay discovery pending the once-briefed dispositive motion. Nevertheless, given the disconnect between the requested discovery and the factual and legal issues material to the resolution of this case, Vanda's demand for additional documents must fail. *See Micro Motion, Inc. v. Kane Steel Co.*, 894 F.2d 1318, 1327 (Fed. Cir. 1990) ("The discovery rules are designed to assist a party to prove a claim it reasonably believes to be viable *without discovery*, not to find out if it has any basis for a claim. That the discovery might uncover evidence showing that a plaintiff has a legitimate claim does not justify the discovery request") (emphasis in original; collecting cases).

At bottom, the Court concludes Vanda's generic (and provisional) request for leave to file an amended complaint and subsequent motion to compel discovery are insufficient and futile efforts to further prolong this case. *See Kemin Foods, L.C. v. Pigmentos Vegetales Del Centro S.A. de C.V.*, 464 F.3d 1339, 1354–55 (Fed. Cir. 2006) ("When a party faces the possibility of being denied leave to amend on the ground of futility, that party must demonstrate that its pleading states a claim on which relief could be granted, and it must proffer sufficient facts supporting the amended pleading that the claim could survive a dispositive pretrial motion.") (citing cases); *Shoshone Indian Tribe of the Wind River Rsrv., Wyoming v. United States*, 71 Fed. Cl. 172, 176 (2006) ("Where the proposed amendment would be subject to the same legal defect found by the court to justify dismissal of claims under the original complaint, leave to amend may be denied.") (first citing *Cultor Corp. v. A.E. Staley Mfg. Co.*, 224 F.3d 1328, 1333 (Fed. Cir. 2000); and then citing *Mitsui Foods, Inc. v. United States*, 867 F.2d 1401, 1404 (Fed. Cir. 1989)). Vanda simply cannot overcome the fundamental hurdles that the dissolution specifications and impurities testing and micronization information do not constitute cognizable property interests under the Fifth Amendment.

CONCLUSION

For the foregoing reasons, defendant's motion for judgment on the pleadings (ECF 29) is GRANTED. Plaintiff's provisional request for leave to file an amended complaint (ECF 47) and motion to compel discovery (ECF 51) are DENIED. The Clerk of Court is directed to enter judgment accordingly. No costs.

[33] The Court proposed to schedule oral argument in mid-November 2024. At the parties' joint request, the matter was continued to December 17, 2024.

It is so **ORDERED**.

Armando O. Bonilla
Judge